

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL
INDUSTRY AVERAGE WHOLESALE
PRICE LITIGATION

MDL NO. 1456

THIS DOCUMENT RELATES TO
State of Montana v. Abbott Labs, Inc., et
al., D. Mont. Cause No. CV-02-09-H-
DWM

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

MEMORANDUM OF BAXTER HEALTHCARE CORPORATION AND BAXTER
INTERNATIONAL INC. IN SUPPORT OF THEIR
MOTION TO DISMISS MONTANA'S SECOND AMENDED COMPLAINT

Montana's Second Amended Complaint (the "Complaint") should be dismissed in its entirety as to Baxter because Montana fails to make any specific allegations of wrongdoing on the part of Baxter.¹ In addition, all of Count I and portions of Counts II through IV should be dismissed as to Baxter's multi-source drugs.

I. THE ENTIRE COMPLAINT IS DEFICIENT UNDER RULE 9(b).

Montana's allegations with respect to all Counts of its Complaint are unduly vague. Montana's claims for deceptive trade practices, Medicaid fraud, and false claims all sound in fraud, and thus all must meet Rule 9(b)'s particularity requirements.

Hayduk v. Lanna, 775 F.2d 441, 443 (1st Cir. 1985). However, Montana fails to particularize Baxter's role in any of the alleged AWP and Best Price violations.

A. Lack Of Specificity In General Allegations

"Where, as here, the complaint involves multiple defendants . . . 'each defendant's role must be particularized with respect to their alleged involvement in the fraud.'" *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp.2d 70, 79 (D. Mass. 1998) (quoting *Kuney Int'l S.A. v. Dilanni*, 746 F. Supp. 234, 237 (D. Mass. 1990)). Instead of doing this, Montana attempts to paint Baxter and all other defendants with broad assertions of wrongdoing. See, e.g., Complaint, ¶¶ 7-10, 12, 173-84, 208, 612-15, 635-43. However, Rule 9(b) "does not permit a complainant to file suit first, and subsequently to search for a cause of action." *Hayduk v. Lanna*, 775 F.2d at 443. In this, its second attempt at filing a Complaint, Montana has yet to assert a viable cause of action against Baxter.

Even the "Baxter-specific allegations" at ¶¶ 296-312 are inadequate. These allegations primarily refer to drugs that are not part of the case. Paragraph 296 and Appendix A contain lists of the drugs for which relief is sought. Paragraphs 298-312 of

¹ The Complaint names both Baxter Healthcare Corporation and Baxter International Inc. as defendants; they are referred to collectively herein as Baxter.

the Complaint make allegations concerning 33 Baxter drugs, only seven of which are listed in ¶ 296 and Appendix A.² And, Montana alleges no details concerning how Baxter might have violated Montana law through its supposed manipulation of the AWP's and/or Best Prices for these seven drugs.

B. Lack Of Specifics To Support Each Count

Count I is a Deceptive Trade Practices Count related to the Medicare (and private payor) "AWP Inflation Scheme" filed on behalf of Montana residents. Montana, however, has not alleged which State residents, if any, purchased any of the Baxter drugs identified in the Complaint.³ The Court's May 13, 2003 Memorandum and Order ("Order") made clear that the class action Plaintiffs were required to allege purchasers for each drug identified in the Amended Master Consolidated Complaint. Order at 45, n. 11. This situation is no different; Montana must allege which residents participating in Medicare Part B (or another health plan utilizing AWP), if any, purchased particular Baxter drugs.⁴ Moreover, both Count I and the AWP Inflation component of Count II (for which Montana seeks recovery on its own behalf) are deficient, because, as

² These are: dextrose, sodium chloride, Factor VIII (Recombinate), Gammagard S/D, gentamycin, heparin, and travasol - - all of which are multi-source drugs.

³ For those residents who are not Medicare recipients, Montana also has not established that the residents paid co-payments based on AWP.

⁴ Montana also is required to allege which residents purchased Baxter drugs for purposes of standing. A plaintiff cannot allege injury attributable to the conduct of Baxter - an essential prerequisite of Article III standing - unless it purchased a Baxter drug. See *Allen v. Wright*, 468 U.S. 737, 751 (1984) (to satisfy Article III standing, "[a] plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief"); *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (factual predicates for standing "must affirmatively appear in the record"). This analysis applies when the plaintiff is a State, seeking recovery on behalf of allegedly aggrieved citizens as *parens patriae*. Because Montana has not established that any of the residents on whose behalf it has filed suit have been injured, it lacks standing to sue on their behalf. For this additional reason, Count I of the Complaint should be dismissed.

described above, no facts are alleged that permit this Court to find that Baxter participated in any such AWP scheme.

Montana has presented no facts to support the portions of Count II and Count III related to the alleged Best Price fraud as to Baxter. *See* Complaint, ¶¶ 603-634. Montana supplies bare bones factual allegations with respect to false AMP and Best Price information related to only four Defendants; none of which is Baxter. Complaint, ¶¶ 617-634. Montana then attempts to lump all other Defendants into this Count by alleging that “each defendant did not report the actual Best Price or AMP, but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians.” Complaint, ¶ 612. The Complaint makes other vague references to unspecified “defendants,” but no specific mention of Baxter. *See, e.g.*, Complaint, ¶¶ 613-15. Absent any allegations of wrongdoing by Baxter, such generalizations are insufficient to support Montana’s Best Price fraud claims as to Baxter.

The False Claims Count (Count IV) of the Complaint also fails for the reasons stated above. Montana neither alleges any submission of a false claim by Baxter, nor links Baxter factually to the AWP or Best Price schemes forming the bases of its False Claims Count.

In sum, Montana’s claims do not meet “even a bare-bones Rule 9(b) test,” *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000), because the Complaint provides no detail of Baxter’s role in the alleged fraud(s). Accordingly, Counts I through IV of the Complaint should be dismissed as to Baxter.⁵

⁵ Count V of the Complaint is a non-substantive request for punitive damages; it is axiomatic that this Count fails as the others do. In addition, for the reasons described in the Consolidated Memorandum, punitive damages cannot be a free-standing Count.

II. COUNT I AND PORTIONS OF COUNTS II, III, AND IV SHOULD BE DISMISSED AS TO BAXTER'S MULTI-SOURCE DRUGS.

This Court dismissed Plaintiffs' claims with respect to multi-source drugs in connection with the Master Consolidated Complaint because multi-source drugs "do not fit the paradigm described in the complaint." Order at 45, n. 11. This also is true with respect to Montana's AWP-related Deceptive Trade Practices counts (Count I and portions of Counts II) and with respect to the AWP-related aspects of the False Claims Count (Count IV). Under Medicare Part B, multi-source drugs are reimbursed based on "the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517; *see also* Complaint ¶ 150. Under this reimbursement methodology, a Defendant cannot gain a competitive advantage by increasing the AWP for its multi-source drugs, and a provider has no financial incentive to prescribe one multi-source drug over another. Multi-source products thus do not fit Montana's "AWP Inflation Scheme" allegations. As a result, Counts I and II should be dismissed as to Baxter's multi-source drugs.

In addition, the Medicaid fraud-related counts (Count III and portions of Counts II and IV), should be dismissed as to Baxter multi-source drugs for which there are three or more suppliers. Medicaid reimbursement for these products is not tied to a product's AWP, but rather "is equal to (i) a reasonable dispensing fee, plus (ii) an amount equal to 150 percent of the lowest AWP published by First DataBank, Medi-Span or the *Red Book* (an amount called the "Federal Upper Limit" or "FUL")." Complaint, ¶ 188, citing 42 C.F.R. § 447.332(b), Mont. Admin. R. 37.86.1101(3).

Finally, Montana alleges that manufacturers allegedly "reported higher prices" for AMP and Best Price, by failing to include discounts and other reductions in

price. Complaint, ¶ 612. Assuming this is true for purposes of this Motion, such reporting would in fact increase, not decrease, the rebates paid on non-innovator multi-source drugs, such as sodium chloride and dextrose, for which rebate payments are 11% of the drugs AMP. See 42 U.S.C. § 1396r-8(c)(3)(A). Thus, the Best Price aspects of Counts II, II, and IV relating to such non-innovator, multi-source drugs also should be dismissed.

CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum and those individual Defendants' memoranda that apply to Baxter, this Court should dismiss Montana's Second Amended Complaint in its entirety as to Baxter. At the very least, Count I and portions of Counts II, III, and IV should be dismissed as to Baxter's multi-source drugs.

Respectfully submitted,

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